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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,687	12/19/2003	Jeffrey A. Hubbell	158264-0003	7788

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EXAMINER

SZEKELY, PETER A

ART UNIT	PAPER NUMBER
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1714

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/743,687

Applicant(s)

HUBBELL ET AL.

Examiner

Peter Szekely

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2005.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 19 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 19 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION***Priority***

1. Applicants have provided an extensive list of related patents and patent applications, which are alleged to provide support for the claimed priority date. To the best of the examiner's ability, there is no clear and convincing evidence that there is explicitly recited support for claim 19. For example, US 5,626,863, Example 16, cited by applicants has two ingredients reacting with each other instead of forming a mixture and the ingredients while being species of an ionically crosslinkable and a covalently crosslinkable component respectively, do not support a claim embracing two entire genera. Applicants are requested to cite the statements in the specifications, with locations included, which provide support for the allegedly unbroken chain of evidence, proving that there is antecedent basis for the entire breadth of claim 19. Until such satisfactory evidence is provided, the effective filing date of the instant application remains August 1, 1995.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 37-58 of U.S. Patent No. 5,334,640. Although the conflicting claims are not identical, they are not patentably distinct from each other because the Reexamination certificate discloses the species for applicants' genera. The presence of a common inventor excludes the possibility of an interference. Mr. Desai cannot be both senior and junior party. Furthermore, the effective filing date of the instant application is 8/1/95.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim 19 rejected under 35 U.S.C. 102(b or e) as being anticipated by Nissinbo Industries EP 0 555 980, Sumino et al. 4,791,061, Feijen 5,041,292 or Kobayashi et al. 5,268,286.

6. Nissinbo Industries has been discussed already. Sumino et al. disclose a method of encapsulating bacteria using a mixture of alginate and polyethylene glycol diacrylate (PEG-DA). See column 3, lines 1-21. Note that this section of the patent describes PEG-DA generically as "polyethylene glycol, wherein a polymeric active group or groups of acrylic acid, methacrylic acid or the like are esterified". As is well known, such a genus includes PEG-DA. Sumino et al. make explicit that such a genus

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includes PEG-GA in column 8, lines 48-68. In Example 4, (column 9, line 5 through column 10, line 22) of Sumino et al., a mixture of alginate and PEG-DA is used to encapsulate the bacteria. Sumino et al. disclose that because toxic chemicals such as crosslinker and plasticizer diffuse away from the microorganisms trapped in the resulting crosslinked alginate and polymerized polyethylene glycol diacrylate, the biological activity of the microorganisms is maintained (column 3, line 47 through column 4, line 9) and the material is thus biocompatible. The ionically crosslinked component is formed from an ionically crosslinkable component such as alginate which may comprise sodium alginate, potassium alginate or ammonium alginate (column 3, lines 11-14). The alginate is mixed with salts of calcium, barium or aluminum to produce the ionically crosslinked component i.e. gelled alginate (Column 3, lines 22-26, column 5, lines 3-13). This is done by dropping sodium alginate solution into a solution of calcium chloride whereupon the divalent calcium ion forms an ionic crosslink between two monovalent alginate molecules. The covalently crosslinked component is formed by polymerizing a covalently crosslinkable component that may comprise a polyethylene glycol diacrylate (PEG-DA) m.w. 300-5000 (column 8, lines 48-55). The covalently crosslinkable component is mixed with a crosslinker such as toluene diisocyanate to produce the covalent crosslinks (further polymerization of the PEG-DA). See column 3, lines 27-36. Alginate, which is disclosed in many places in Sumino et al., is a well-known polysaccharide. Feijen teaches a proteinaceous component, which is covalently crosslinkable and a polysaccharide, which is ionically crosslinkable blended together in an aqueous solution in a proportion of about 10:90 to 90:10, in claim 1. Kobayashi et al.

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describe a method of encapsulating a biocatalyst, e.g. mammalian cells using a mixture of a covalently crosslinkable component and the ionically crosslinkable component. A mixture of the covalently crosslinkable component and the ionically crosslinkable component is dropped in a salt solution so that the ionically crosslinkable component ionically crosslinks with the salt to form a gel. The resulting gel is then irradiated, preferably with the salt to form a gel. The resulting gel is then irradiated, preferably with a light source such as sunlight that does not contain light at wavelengths above 320 nm to prevent damage to the encapsulated biocatalyst. The irradiation causes the covalently crosslinkable component to covalently crosslink, completing the encapsulation of the biocatalyst. See column 2, lines 3-20 and column 4, lines 57-64. The ionically crosslinkable component may comprise alginic acid (column 2, lines 33-36). The ionically crosslinkable component is e.g. sodium alginate which may be mixed with the solution of biocatalyst (e.g. a mammalian cell) and covalently crosslinkable component and dropped into an aqueous medium containing a salt. The sodium alginate will then gel by forming an ionic crosslink with the salt (column 3, lines 49-59). The covalently crosslinkable component may comprise a polymer grafted with a saponified polyvinyl acetate. The covalently crosslinkable component is treated with actinic rays (preferably light having a wavelength greater than 320 nm) to convert the crosslinkable component into a covalently crosslinked component (column 2, lines 27-68; column 4, lines 57-64). Alginate, which is disclosed in many places in Kobayashi et al. (e.g. column 2, lines 33-36) is a well-known polysaccharide. Applicants' claim is not

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novel. Both 102(b) and 102(e) rejections were made to cover any effective filing date, which may result from further prosecution.

7. Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by Desai et al. 5,550,178, Soon-Shiong et al. 5,705,270, Soon-Shiong et al. 5,700,848, Gunther et al. 5,736,595, Soon-Shiong et al. 5,837,747, Soon-Shiong et al. 5,846,530 or Mathiowitz et al 5,985,254.


8. All references have discussed in the previous Office action. Since the effective filing date of the instant application is 8/1/95 all of the above references read on applicants' invention. Applicants' claims are not novel.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Szekely whose telephone number is (571) 272-1124. The examiner can normally be reached on 7:00 a.m.-5:30 p.m. Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Peter Szekely
Primary Examiner
Art Unit 1714

P.S.
6/28/05